K132406

APR 18 2014

510(k) Summary

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 03/10/2014

1. Submission Applicant / Submitter

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2. Submission Correspondent

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3. Device

- Trade Name: Element™ V Blood Glucose Monitoring System
- Classification Name: Glucose test system, Quality control material (assayed and unassayed)
- Classification regulation: 21 CFR Part 862.1345, 21 CFR Part 862.1660
- Product Code: NBW, CGA, JJX

4. Predicate Device:

Element™ plus Blood Glucose Test System (K103021), Infopia Co., Ltd.

5. Description:

The Element™ V Blood Glucose Monitoring System consists of the meter, test strips and control solutions (Level 1, Level 2 and level 3). The blood glucose test system is an in vitro diagnostic device designed for measuring the concentration of glucose in whole blood sample by means of an electrical current produced in the test strip and sent to the meter for measurement.

6. Indications for use:

The Element™ V Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger, palm, hand, upper-arm, forearm, calf, and thigh. The Element™ V Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The Element™ V Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of or screening for diabetes and/or for neonatal use. Alternative site testing should be done only during steady–state times (when glucose is not changing rapidly).

The Element™ V test strips are for use with the Element™ V meter to quantitatively measure glucose (sugar) in fresh capillary whole blood. Fresh capillary whole blood samples may be drawn from the finger, palm, hand, upper-arm, forearm, calf and/or thigh.

The Element™ V control solutions are for use with the Element™ V meter and the Element™ V test strips to check that the meter and test strips are working together properly and the test is performing correctly.

This meter contains some speaking functions but has not been validated for use by the visually impaired. By adding the voice function, users can hear test results, setting conditions and warning messages (errors) while performing the test. This added function is intended to aid users for their convenience.

7. Comparison to the Cleared Device

The modifications are the changes in the strip size, the material of the test strip vial, the test strip quantity in the vial, the appearance of the meter housing and the strip cover, and also adding an error message.

Other than these modifications, the modified meter has the following similarities to the cleared device:

- has the same intended use,
- uses the same operating principle,
- adopts the same use environment and calibration method.

8. Performance Data

Clinical: The clinical performance evaluation using the Element™ V Blood Glucose Monitoring System was conducted for purpose of validating the consumer use for the accuracy.
Test results showed substantial equivalence.

Non-clinical: Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the Element™ V Blood Glucose Monitoring System. The device passed all of the tests based on pre-determined Pass/Fail criteria.

Disinfection Study: Disinfectant CaviWipes with the EPA registration number of 46781-8 has been

Validated demonstrating complete inactivation of live virus of use with the meter and the reusable lancing device. There was also no change in performance or in the external materials of the meter and the lancing device after 1,095 cleaning/disinfection cycles designed to simulate 3 years of device use.

9. Conclusion

The conclusion drawn from the clinical and nonclinical tests is that the Element™ V Blood Glucose Monitoring System is as safe, as effective and performs as well as the legally marketed predicate device, Element™ plus Blood Glucose Test System (K103021).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

INFOPIA CO., LTD
C/O PRISCILLA CHUNG
2651 E CHAPMAN AVE STE 110
FULLERTON CA 92833

April 18, 2014

Re: K132406
Trade/Device Name: Element V Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: March 10, 2014
Received: March 14, 2014

Dear Ms. Priscilla Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k132406

Device Name
Element™ V Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Element™ V Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger, palm, hand, upper-arm, forearm, calf, and thigh. The Element™ V Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The Element™ V Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of or screening for diabetes and/or for neonatal use. Alternative site testing should be done only during steady–state times (when glucose is not changing rapidly).

The Element™ V test strips are for use with the Element™ V meter to quantitatively measure glucose (sugar) in fresh capillary whole blood. Fresh capillary whole blood samples may be drawn from the finger, palm, hand, upper-arm, forearm, calf and/or thigh.

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Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Stayce Beck -S